



## Nizoral (ketoconazole): Drug Safety Communication - Potentially Fatal Liver Injury, Risk of Drug Interactions and Adrenal Gland Problems

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FDA警告Nizoral (ketoconazole)口服錠可能造成嚴重肝損傷和腎上腺的問題，並可能與其他藥品產生有害的交互作用。FDA已核准其仿單修改，增加新的用藥指示，以解決安全問題。Nizoral口服錠不可作為任何黴菌感染的一線治療。Nizoral口服錠應該用於其他抗黴菌藥治療無效或無耐受性的特定黴菌感染(即endemic mycoses)。

### 肝損傷 (肝毒性)

Nizoral錠劑可能引起肝損傷，而導致肝臟移植或死亡。FDA強烈建議此藥不可以用於有肝臟疾病的患者，且使用的患者應定期評估、監視肝毒性。

### 腎上腺功能不全

Nizoral錠劑可能降低體內腎上腺皮質固醇的生成，而導致腎上腺皮質功能不全。

### 藥物相互作用

Nizoral錠劑可能與其他藥品產生嚴重、具潛在致命性的交互作用，如心臟節律的問題。

### 建議

當潛在益處大於風險，對其他治療無耐受性，且為危及生命黴菌感染，才能使用Nizoral錠劑。給予口服ketoconazole之前，醫護人員應評估病人肝功能；治療期間監測ALT。

當患者腎上腺皮質功能不全或介於正常值邊緣，或長期處在壓力下(如major surgery, intensive care)，應檢測患者腎上腺皮質功能。

檢視所有與Nizoral錠劑具交互作用的藥物。

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**AUDIENCE:** Internal Medicine, Infectious Disease

**ISSUE:** FDA is taking several actions related to Nizoral (ketoconazole) oral tablets, including limiting the drug's use, warning that it can cause severe liver injuries and adrenal gland problems, and advising that it can lead to harmful drug interactions with other medications. FDA has approved label changes and added a new Medication Guide to address these safety issues. As a result, Nizoral oral tablets should not be a first-line treatment for any fungal infection. Nizoral should be used for the treatment of certain fungal infections, known as endemic mycoses, only when alternative antifungal therapies are not available or tolerated.

### *Liver Injury (Hepatotoxicity)*

Nizoral tablets can cause liver injury, which may potentially result in liver transplantation or death. FDA has revised the Boxed Warning, added a strong recommendation against its use (contraindication) in patients with liver disease, and included new recommendations for assessing and monitoring patients for liver toxicity.

### *Adrenal Insufficiency*

Nizoral tablets may cause adrenal insufficiency by decreasing the body's production of corticosteroids.

### *Drug Interactions*

Nizoral tablets may interact with other drugs a patient is taking and can result in serious and potentially

life-threatening outcomes, such as heart rhythm problems.

**BACKGROUND:** Nizoral (ketoconazole) is indicated for the treatment of fungal infections when alternatives are not available or not tolerated. The topical formulations of Nizoral have not been associated with liver damage, adrenal problems, or drug interactions. These formulations include creams, shampoos, foams, and gels applied to the skin, unlike the Nizoral tablets, which are taken by mouth.

**RECOMMENDATION:** Nizoral tablets should be used only for the treatment of certain life-threatening mycoses when the potential benefits outweigh the risks and alternative therapeutic options are not available or tolerated. Healthcare professionals should assess the liver status of the patient before starting oral ketoconazole, and monitor serum ALT levels during treatment. Adrenal function should be monitored in patients with adrenal insufficiency or with borderline adrenal function and in patients under prolonged periods of stress (major surgery, intensive care, etc.). Review all concomitant medications for the potential for drug interactions with Nizoral tablets.